K092928

510(k) Summary

Submission Date:	18 September 2009
Submitter:	DiversiLabs, LLC PO Box 107 Huntingdon Valley, PA 19006
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Official Contact:	Thomas Kroenke Principal Consultant Speed To Market, Inc. PO Box 3018 Nederland, CO 80466 USA tkroenke@speedtomarket.net 303 956 4232
Manufacturing Site:	DiversiLabs, LLC PO Box 107 Huntingdon Valley, PA 19006
Trade Name:	Dose Volume Histogram (DVH) Evaluator
Common Name:	Accessory to a Radiation Therapy Treatment Planning System
Classification Name:	System, Planning, Radiation Therapy Treatment
Classification Regulation:	21 CFR §892.5050
Product Code:	MUJ

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Substantially Equivalent Devices:	*DiversiLabs Model*	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
	Dose Volume Histogram (DVH) Evaluator	K000478	Accuray, Inc MultiPlan v2.1 Radiation Treatment Planning System
		K091492	Varian Medical Systems, Inc. Eclipse Treatment Planning System

Device Description: The Dose Volume Histogram (DVH) Evaluator is a stand alone software application product for use on a personal computer (PC) intended to aid with comparing radiation therapy treatment plans to applicable dose tolerance limits, and for recording followup patient response and symptoms.

The DVH Evaluator is intended for use by trained medical physicists, physicians, or dosimetrists. The results must be evaluated by qualified personnel before a patient treatment. It is the responsibility of the medical physicist, physician or dosimetrist to determine whether the displayed limits and dose is adequate for a particular patient.

The DVH Evaluator imports a file produced by a radiation TPS in the format of an industry standard Dicom-RT™ or vendor specific file, which contains information about a treatment. The file contains information related to the radiation dose volume for patient anatomical structures.

After importing the TPS information, DVH Evaluator allows the user to select dose tolerance limits and overlay them on the dose volume information. If the dose to any contoured critical anatomical structures exceeds any of the tolerance limits, warnings are displayed on the plots. This enables clinical users to conveniently and comprehensively compare treatment plans to the user- selected dose tolerance limits. The DVH Evaluator does not control any radiation delivery devices and does not allow the export of dose limit information.

The Followup Evaluator is an optional module of the DVH Evaluator which conveniently enables the user to record any response or symptoms that the patient experiences, either prior to or following treatment. This information is stored in the same database along with the DVH data for each patient for subsequent analysis. This enables convenient offline feedback to assess whether the dose tolerance limits are optimal for each clinic.

Device Description (cont.):	The DVH Evaluator is provided to the customer on a CD or downloaded from www.DiversiLabs.com. A PC is not provided with the product. The PC requires Microsoft Windows XP or Windows Server 2003 Operating System, a minimum of 500 MHz microprocessor speed, a minimum of 256 MB RAM and 1 GB available hard drive space. Display requirements include 1024 x 768 minimum resolution with 1280 x 1024 preferred.
Intended Use:	The DVH Evaluator system is intended to aid with comparing radiation therapy treatment plans to applicable dose tolerance limits, and for recording followup patient response and symptoms.
Technology Comparison:	The DVH Evaluator is based on the same DVH data that all modern TPSs already support. The dose tolerance limits are stored in a text ASCII file. The DVH Evaluator imports the DVH information from the TPS, imports the dose tolerance limits from the ASCII file, and plots the user-selected limits on the same graph. Simple numerical interpolation is used to determine if any of the specified limits are violated. It is the responsibility of the medical physicist, physician or dosimetrist to determine whether the dosimetric accuracy is adequate for a particular patient, and to make the final decision regarding treatment. The benefit of the DVH Evaluator is to make quick, comprehensive assessment of a treatment plan during the iterative planning process.
Performance Testing:	
Software Testing	Software for the DVH Evaluator was designed and developed according to a robust software development process, and was rigorously verified and validated. Test results indicated that the DVH Evaluator complies with its predetermined specification.
Conclusion	Based upon a comparison of the devices and performance testing results, the DiversiLabs DVH Evaluator is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

DiversiLabs, LLC
% Mr. Thomas Kroenke
Official Correspondent
Speed to Market, Inc.
2235 East Flamingo Road, Suite 201G
LAS VEGAS NV 89119

DEC 16 2009

Re: K092928
Trade/Device Name: DiversiLabs Dose Volume Histogram (DVH) Evaluator
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: December 4, 2009
Received: December 9, 2009

Dear Mr. Kroenke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092928

Device Name: DiversiLabs Dose Volume Histogram (DVH) Evaluator

Indications for Use: The DiversiLabs Dose Volume Histogram (DVH) Evaluator is intended to aid with comparing radiation therapy treatment plans to applicable dose tolerance limits, and for recording followup patient response and symptoms.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K092928